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09/226,597	01/07/1999	JULIO PIMENTEL	ANIT0018U-US	9844

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EXAMINER	
GABEL, GAILENE	
ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/226,597	PIMENTEL, JULIO	
	Examiner	Art Unit	
	GAILENE R. GABEL	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-5,12-19,22-25 and 32-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,12-19,22-25 and 32-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Art Unit: 1641

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed February 14, 2008 is acknowledged and has been entered. Claims 1, 3, 12, 16, 25, 32, 34, and 35 have been amended. Claims 26-31 and 36-42 have been cancelled. Accordingly, claims 1-5, 12-19, 22-25, and 32-35 are pending. Claims 1-5, 12-19, 22-25, and 32-35 are under examination.

Rejections Withdrawn

2. All rejections not reiterated herein have been withdrawn.

3. The rejections of claims 26-31 and 36-42 are now moot in light of Applicant's cancellation of the claims.

4. In light of Applicant's amendment, the rejection of claims 3, 12, 34, and 35 under 35 U.S.C. 112, second paragraph, is hereby, withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. For purposes of prior art rejection, the claims, as written, are interpreted as follows. Note that unpatented claims are given the broadest reasonable interpretation consistent with the specification.

A. Claims 1-5, 12-15, and 32-35 are drawn to a method for decreasing fat absorption in mammals using liposome-encapsulated anti-lipase antibodies.

B. Claims 16-19 and 22-24 are drawn to a composition for decreasing fat absorption in mammals.

C. Claim 25 is drawn to a method of making a composition for decreasing fat absorption in mammals.

From here on, liposome-encapsulated anti-lipase antibodies are LE anti-lipase Abs.

6. Claims 1-5, 12-19, 22-25, and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US Patent 5,725,873, filing date July 22, 1996) in view of Ohkaru et al. (Application of two monoclonal antibodies to either an immunosorbent enzyme assay or a competitive binding enzyme immunoassay for human serum pancreatic lipase, Clin. Chim. Acta, 182 (3): 295-300 (1989), Abstract Only).

Cook et al. disclose a method of feeding to an animal a food composition comprising a liposome-encapsulated antibody (Abstract). The antibody may be provided in solution in a wet state, in an aqueous or lipid carrier, i.e. liposome-encapsulation, and may also be directly applied to the pellet core without a

carrier (freeze-dried) such as a powder (column 1, lines 32-43 and Example 2). The antibody is encapsulated in liposomes having an inner core comprising non-fat nutrients and an outer layer of fat which contains effective amount of antibodies (see column 1, lines 52-65; column 2, lines 22-46).) The antibody is avian, i.e. obtained from egg of a hen which has been injected with antigen that results to the production of its corresponding antibodies (column 1, lines 34-39 and column 2, lines 6-9). The food composition is made by forming a nutrient mixture and then depositing the liposome-encapsulated antibody into the pellet core (column 1, line 66 to column 2, lines 1-5 and 10-23). The food content comprises protein and carbohydrate may also include vitamins and dietary lipid (column 2, lines 27-34 and 51-67). The food composition and method are prepared as animal feed for use in either mammals (pets), or avians such as ducks, chickens, and turkeys (see Example 3; Table 1; and column 4, lines 34-37). The food composition containing the avian antibody is fed to the animal in an amount that may be effective in passively immunizing the animal or otherwise enhancing the efficiency of feed conversion by the animal (column 2, lines 35-38). According to Cook et al., the antibodies may be any one which can which can alter physiological processes that adversely affect growth and efficiency. The antibodies can be those that are against diseases or specific for endogenous antigens present in the digestive system that regulate food intake and gastrointestinal motility (column 2, lines 39-47).

Cook et al. differ from the claimed invention in failing to teach that the antibody is anti-lipase antibody directed against pancreatic lipase antigen.

Ohkaru et al. teach raising two monoclonal antibodies against pancreatic (gut) triacylglycerol lipase. One of the monoclonal antibodies specifically inhibited the lipase antigen (Abstract).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the anti-lipase monoclonal antibody raised by Ohkaru against pancreatic lipase antigen into the

liposome-encapsulation-based feed composition and method taught by Cook, because Cook's method is generic in the type of gastrointestinal-type antibody used for binding its gastrointestinal antigen, whether it would be those effective in passively immunizing the animal and enhancing the efficiency of feed conversion by the animal, or those which can alter physiological processes that adversely affect growth and efficiency, or those that are against diseases or those that are specific for endogenous antigens (column 2, lines 35-47) such as pancreatic lipase antigen as taught by Ohkaru present in the digestive system that are deemed to regulate food intake and gastrointestinal motility, including by way of inhibition of the antigen as in the teaching of Ohkaru.

Cook et al. and Ohkaru et al. do not disclose that the composition contains 25 to 1000 mg of liposome encapsulated anti-lipase antibodies per kilogram of the animal food, as recited in claims 14, 15, 17, and 23.

Cook et al. specifically disclose administering safe and effective amounts of antibody that would help protect the animal from disease or other antigens that can adversely affect animal's growth or the efficiency of the animal to convert feed into desirable body tissue. Therefore, the amount of liposome-encapsulated anti-lipase antibody contained in a food composition should be a safe and effective quantity.

Such ranges of antibody concentrations in food composition, are rendered as result effective variables, which the prior art references have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233,235-236 (C.C.P.A. 1955). "No

invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215,218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in claims 14, 15, 17, and 23 are for any particular purpose or solve any stated problem and the prior art teaches that effective concentrations of antibodies or compounds used may vary according to the animals being fed and/or their characteristics, absent unexpected results, it would have been obvious for one of ordinary skill to discover the safe and effective amounts of antibodies and compounds used for the composition and method disclosed by the prior art by normal optimization procedures.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5, 12-19, 22-25, and 32-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In this case, the specification does not appear to provide any literal support for the recitation of "[methods or compositions] for decreasing fat absorption in mammals". Nowhere in the specification provides a discussion, much less a description of how decrease in fat absorption in animals relates to

liposome encapsulated anti-lipase antibodies in Applicant's disclosure; thereby, failing to provide literal support for such recitation. "Decreasing fat absorption" is not adequately supported in the specification because it does not necessarily flow from the limited discussion of "inhibition of weight gain" in the specification, because they are not commensurate in scope. Furthermore, none of the originally filed claims recited the limitation in question. Recitation of claim limitation lacking literal support in the specification or originally filed claims constitutes new matter.

Response to Arguments

8. Applicant's arguments filed February 4, 2008 have been fully considered but they are not persuasive.

A) Applicant argues that the Cook reference does not teach encapsulation of the antibody per se, but rather only teaches the antibody complex being coated with fat, and mere coating is not equivalent to encapsulation process. According to Applicant, pelleted feed is often coated with fat to increase its fat/energy content, i.e. "fat coating" which soaks into the feed and does not encapsulate the feed pellet to form a "liposome" as claimed, whereupon a liposome is a spherical vesicle composed of a bilayer membrane, i.e. phospholipid bilayer, thus requiring formation of molecular structure. Applicant states that fat coating will not be expected to protect internal core.

In response, Applicant's argument is not persuasive because further evaluation of Cook provides that the liposome formation process and antibody encapsulation is consonant to that taught by Cook. To wit, Applicant's disclosure at page 1, lines 25-26 and Example 2 provide that "chicken antibodies can be protected from stomach acidity and pepsin hydrolysis by encapsulating them within lecithin/cholesterol

liposomes, a process known and conventional in the art (Shimizu et al.). Cook et al. teach that the antibodies in the method are specifically encapsulated (column 1, lines 62-65; column 2, lines 1-5, 12-23, 26-32). The fat used to encapsulate and protect antibody in the Cook reference can be any fat or lipid (cholesterol) (column 2, lines 57-62) including oil derivatives such as lecithin (column 3, line 11). Additionally, nowhere in Applicant's disclosure appears to provide that the liposome as claimed used to encapsulate the instant anti-lipase antibody is specifically a phospholipid bilayer that forms a molecular structure.

In response to Applicant's argument that Cook et al. is distinct from the claimed invention because the Cook reference only teaches "fat-coating" which soaks into the feed and does not encapsulate the feed pellet to form a liposome as claimed, the argument is not on point because the claims recite liposome encapsulation of antibodies and not liposome encapsulation of the feed pellet.

Contrary to Applicant's argument that Cook's fat coating will not be expected to protect internal core because it soaks into the feed, is also not persuasive because Cook's liposomes used for encapsulation appears to be consonant to the teaching of Applicant. Moreover, Cook et al. specifically teach that the feed composition would have an inner core comprised of nutrients (proteins and carbohydrates) and an outer layer of fat containing the antibodies encapsulated therein, and that the composition's advantage is that the outer layer of fat in which the antibodies are encapsulated to help protect the antibodies from stomach acid and intestinal enzymes (column 1, line 62 to column 3, line 5 and lines 10-23). Cook et al. also teach that the feed particles comprise an inner core which primarily contains the desired non-fat material (protein and carbohydrate) and the outer layer of fat which contains the antibodies encapsulated therein; although the inner may (selectively) also contain fat, if desired (column 2, lines 27-34).

B) Applicant argues that the antibody of Cook et al. is CCK which is not related to anti-lipase antibodies of the claimed invention. Applicant contends that CCK is not anti-lipase antibody.

In response, Cook et al. is generic in the types of antibodies used for incorporation into the feed, so long as they are those that are against antigens present in the gastrointestinal tract. This is reflected throughout the specification of Cook et al. CCK is only embodied in Example 2. As such, it does not apparently exclude the anti-lipase antibody specific to pancreatic lipase as taught by Ohkaru.

C) Applicant argues that Ohkaru et al. does not describe feeding anti-lipase antibodies to an animal or inhibiting fat absorption in any way, and specifically contends that only one of the antibodies inhibited lipase.

In response to applicant's arguments against the Ohkaru et al. individually as a reference failing to show feeding LE anti-lipase Abs, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the rejection is based on the combined teaching of Cook et al. with Ohkaru et al. to render the claimed invention obvious. Cook et al. is relied upon for teaching food compositions used to feed animals containing antibodies to gastrointestinal antigens encapsulated therein. Ohkaru et al. is relied upon for combination with Cook et al. for teaching generation of gastrointestinal, i.e. pancreatic anti-lipase antibody from pancreatic lipase antigen, that is able to specifically inhibit the lipase antigen that is present in the gut. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to encapsulate the anti-lipase monoclonal antibody raised by Ohkaru against pancreatic lipase antigen that

specifically inhibited the pancreatic lipase antigen, for incorporation into the liposomes taught in the method of Cook, because Cook is generic in the type of antibodies used for incorporation into the feed, so long as they have specificity and reactivity with gastrointestinal antigens present in the gut for whatever purposes they are intended for use.

In as far as intended use recited in the preamble, the recitation "for decreasing fat absorption in mammals" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951)

9. No claims are allowed.

10. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory

action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

April 14, 2008